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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,409	12/30/2003	Johanna Jacoba Maria Meulenberg	01-1793-4-C4	4880

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Michael P. Morris
Boehringer Ingelheim USA Corporation
900 Ridgebury Road
Ridgefield, CT 06877-0368

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
01/27/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/750,409	MEULENBERG ET AL.	
	Examiner	Art Unit	
	MYRON G. HILL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the papers filed 12/22/10.

This action is on claims 21, 22, 24, and 32-37.

. **The finality of the previous Office Action is withdrawn** and new rejection(s) follow.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 requires a full length infectious clone that expresses a heterologous Orf7 of ATCC 2332.

Applicant has pointed to support and the rejection is withdrawn.

Rejections New

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(MPEP 2163) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material. In re Herschler, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in In re Kaslow, 707 F.2d 1366, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). See also MPEP § 2163 - § 2163.04.

The claims recites "virulence" and "virulence marker."

The specification does not disclose infectious clones with the properties claimed.

The prior art does not teach what mutations can lead to virulence or virulence markers. The specification does not teach what derivatives or modifications have these properties or what mutations or changes can be made to change the virulence or virulence marker.

The mere contemplation of the claimed genus in the specification is not sufficient to support the present claimed invention directed to a genus of "virulence" and "virulence markers."

The specification does not set forth the written description commensurate with the scope of the claims. There is not enough information about it in literature to guide the one of ordinary skill in the art to make what is claimed. Thus, the disclosure fails to provide a meaningful disclosure and possession of the broad scope of the now claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by Wensvoort *et al.* (WO 92/21375) as evidenced by Meulenberg *et al.* (J Virology 1998 Vol. 72, pages 380-387, from IDS, copy in parent application 09874626).

Applicant argues that Wensvoort *et al.* does not disclose SEQ ID# 18 at the 3 prime end of the genome and that the clone of Wensvoort *et al.* is not infectious.

Applicant's arguments have been fully considered and not found persuasive.

Wensvoort *et al.* claim 4 describes a vector corresponding to the isolate deposit CNCMI-1102. This vector corresponds to the infectious agent, not the sequence disclosed in Wensvoort *et al.*

The SEQ ID# 18 argued by applicant is shown by Meulenberg *et al.* (J Virology 1998 Vol. 72, pages 380-387, from IDS, copy in parent application 09874626) to be at the 5 prime end of LV, see Table 1). Thus, the SEQ ID# 18 at the 5 prime end of the PRRSV genome is an inherent feature of the virus of the deposit which is possessed by Wensvoort *et al.* Claim 4 of the WO document teaches a recombinant vector comprising the LV of PRRSV Deposit I-1102.

Thus, Wensvoort *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al.* (WO 92/21375), Moormann *et al.* (Journal of Virology 1996, Vol 70, pages 763-770).

Applicant argues that prior art would not result in the invention because it does not teach SEQ ID# 18, that the specification teaches that there are problems with RNA synthesis (para 13) and 5 prime cap structure make infectious clones (para 68), and that prior to the instant application, no one made an infectious clone over 12KB.

Applicant's arguments have been fully considered and not found persuasive.

Wensvoort *et al.* in claim 4 describes a vector corresponding to the isolate deposit CNCMI-1102. This vector corresponds to the infectious agent, not the sequence disclosed in Wensvoort *et al.* and the virus itself comprises SEQ ID# 18 on the 5 prime terminus as indicated above.

As discussed previously, the prior art makes it clear that full length clones are needed and one of ordinary skill in the art would make full length clones.

Thus, the claims are unpatentable over Wensvoort *et al.* and Moormann *et al.*

Claims 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al.* (WO 92/21375), and Moormann *et al.* (Journal of Virology 1996, Vol 70, pages 763-770) as applied to claims 21 and 24, further in view of Drew *et al.*

Wensvoort *et al.* and Moormann *et al.* have been discussed above and previously and teach a recombinant vector comprising the sequence of Deposit I-1102.

Wensvoort *et al.* and Moormann *et al.* also teach that polyclonal sera can differentiate PRRSV strains (Tables 7 and 8, and page 19).

They do not teach specific differences in protein reaction.

Drew *et al.* has been discussed previously and teaches that monoclonal antibodies to ORF 7 can differentiate different strains of PRRSV (see discussion).

One of ordinary skill in the art would have been motivated to make a marker virus for vaccine use with serological changes in the virus because Moormann *et al.* teach that marker vaccines are useful (page 769, column 2, middle). It would have been obvious to switch ORF7s with other known PRRSV because the proteins can be differentiated in a serologic assay.

Thus, it would have been prima facie obvious to modify the recombinant vector comprising the sequence of Deposit I-1102 with serological markers using ORF7 because those modifications were known in the art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

/M. G. H./
Examiner, Art Unit 1648